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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,247	01/30/2001	Francesco Parenti	199509US0PCT	4708

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	7

DATE MAILED: 05/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,247	PARENTI ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-18 and 20-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicants' election of Group I (Claims 1-5, 9-18, 20-35) with traverse is acknowledged, as are the elected species (soybean oil, and egg yold phospholipids). However, applicants' election is not fully responsive. The first specie is that of a specific ramoplanin. Rather than electing one ramoplanin, applicants have elected six of them. Compliance with the election of species requires election of a single ramoplanin, i.e., **one** "R" group and **one "R'"** group.

Applicants have traversed the restriction by arguing that applicants who file under 371 enjoy "immunity" from restriction. However, this is not correct. If one of the claimed embodiments fail to "define a contribution" over the prior art, lack of unity may be found by the examiner. While novelty may indeed accrue to some embodiments, the assertion is that claim 1, at least, is not novel in all embodiments. Moreoever, claim 1 neither requires nor suggests the presence of a triglyceride. PCT rules, when they apply at all, pertain to compositions (or compounds), methods of using those compositions, and methods of making those compositions. PCT rules do not state that when one claim is drawn to genus "X" of compositions, and another claim is drawn to genus "Y" of compositions, that examiners are necessarily barred from restricting between them. The restriction is still maintained.

*

An abstract is required, and does not appear to be present.

*

Claims 1-5, 9-18, 20-35 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 should begin with the indefinite article (**A** pharmaceutical formulation).
- Claim 1 recites (third line from last) the phrase "fat emulsion product". How is a "fat emulsion" different from a "fat emulsion product"....? A related matter concerns the phrase "the oil phase" (last line of the claim). This phrase lacks antecedent basis.
- In claim 7, last line, the abbreviation "q.s." is used. This abbreviation should be spelled out.
- Claim 14 recites "agents that are susceptible to ramoplanin". First, what is meant by "agents" other than bacteria? As for being "susceptible to ramoplanin", what is encompassed other than inhibition of bacterial proliferation?
- Claim 15 recites the term "serious". Does this mean life-threatening, or something else? The phrase "such as" fails to set the metes and bounds of the claim.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f)

and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Ciabatti (EP 0,337,203) in view of (a) Kurihara (USP 4,990,337) or (b) Sekine (USP 5,968,899) or (c) Ishida (USP 5,891,846).

Ciabatti discloses (page 7, lines 50-51) that ramoplanin can be formulated into a gel, a liquid solution for injection , a cream or a suspension. The reference does not specifically suggest an emulsion. Each of the secondary references teaches the use of an emulsion to enhance bioavailability. None of the secondary references mentions ramoplanin. Thus, it would have been obvious to one of ordinary skill to formulate ramoplanin into an emulsion. The phrase "for intravenous administration" (instant claim 1) is noted, but this intended use phrase does not necessarily distinguish formulations intended for other routes of administration.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600